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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

BAKER, A

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/060,409

Applicant(s)

Sah et al.

Examiner  
Anne-Marie Baker, Ph.D.

Group Art Unit  
1632

File Copy

☒ Responsive to communication(s) filed on Sep 8, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 6-16 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 10 and 11 is/are allowed.

☒ Claim(s) 6-9 and 12-16 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2, 7, 9

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1632

### DETAILED ACTION

The response filed on September 8, 2000 (Paper No. 10) has been entered. Applicants' election, without traverse, of Group II, Claims 6-39 in Paper No. 10 is acknowledged. Applicants have cancelled Claims 1-5 and 17-46. The elected invention is drawn to a method for producing a conditionally-immortalized dorsal root ganglion progenitor cell, cells produced by the method, and methods for using the immortalized cells of the invention. The claims are examined only to the extent that they encompass the elected subject matter.

Accordingly, pending Claims 6-16 are examined herein.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 and 12-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a conditionally-immortalized dorsal root ganglion progenitor cell by transfecting the cell with DNA encoding a sectable marker and an oncogene and the cell produced by said method, does not reasonably provide enablement for a method for producing a conditionally-immortalized dorsal root ganglion progenitor cell by transfecting the cell with DNA encoding a sectable marker and any growth-promoting gene and the cell produced by said method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Art Unit: 1632

The specification fails to provide an enabling disclosure for the use of any growth-promoting gene because the specification only teaches the use of oncogenes, and moreover, only contemplates the use of oncogenes for the immortalization of cell lines. The specification does not teach any other growth-promoting genes or any other class of growth-promoting genes. The specification states that “[w]ithin certain embodiments, the growth-promoting gene is an oncogene such as v-myc” (p. 2, lines 23-24). The specification further states that “PNS progenitor cells may be conditionally immortalized by transfection of the plated cells with any suitable vector containing a growth-promoting gene (i.e., a gene encoding a protein that, under appropriate conditions, promotes growth of the transfected cell)” (p. 11, lines 9-11). However, the only growth-promoting genes contemplated in the specification are oncogenes. The specification teaches that “[i]n a preferred embodiment the growth-promoting gene is an oncogene such as, but not limited to, v-myc, N-myc, c-myc, p53, SV40 large T antigen, polyoma large T antigen, E1a adenovirus or E7 protein of human papillomavirus” (p. 11, lines 15-17). No other class of growth-promoting genes is taught in the specification. The working examples are directed exclusively to the use of the v-myc oncogene (Examples 1-7). The prior art teaches the routine use of oncogenes for the immortalization of cell lines, but does not describe the routine use of any other type of gene for immortalization. Watson et al. (1992) discuss the immortalization of cells, but teaches the use of oncogenes exclusively. Thus, the use of genes other than oncogenes was not routine in the art. The teachings in the specification are limited to the use of oncogenes for the immortalization of dorsal root ganglion progenitor cells and the prior art teaches only the routine use of oncogenes for the immortalization of cell lines. The prior art does not teach the routine use of other growth-promoting genes.

Given the limited teachings in the specification, the state of the prior art, the broad scope of the claims with respect to the type of gene to use for immortalization, and the limited working examples directed

Art Unit: 1632

exclusively to the use of v-myc for immortalization of dorsal root ganglion progenitor cells, undue experimentation would have been required for one skilled in the art to make and use the full scope of the claimed invention. Accordingly, limitation to the use of oncogenes and cells transfected with and immortalized by oncogenes, rather than any growth-promoting gene, is appropriate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite because it recites improper Markush terminology. The claim recites "or" between members of the Markush group, but proper Markush terminology requires the use of "and" between members of the Markush group. Furthermore, the language "selected from the group consisting of substrates comprising one or more of..." is confusing. Use of the phrase "wherein the first and second surfaces comprise one or more of the substrates selected from the group consisting of..." is recommended.

Claims 12-16 are indefinite in their recitation of "capable of" because a capability is a potential and not an actual property or physical limitation. Recitation of the term "capable" in the claims implies that the cells can differentiate into the specified cell type under certain prescribed conditions, but the claims do not delineate the conditions under which said differentiation actually occurs.

Claims 13 and 14 are indefinite in their recitation of "transfected" because there is no indication of what it is that the cell is transfected with.

Art Unit: 1632

*Conclusion*

Claims 10 and 11 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne-Marie Baker, Ph.D.

Anne-Marie Baker  
Patent Examiner